UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Civil Action No. MDL No. 2326

ADVAMED'S OBJECTIONS AND RESPONSES
TO PLAINTIFFS' RULE 45 SUBPOENA

Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure, non-party Advanced Medical Technology Association ("AdvaMed") submits the following responses and objections to the Subpoena that Plaintiffs served on January 23, 2013 ("the Subpoena"). The Subpoena seeks massive discovery in connection with Plaintiffs' claims that Defendants defectively manufactured, defectively designed, failed to warn, negligently designed, manufactured, and marketed, and breached warranties in connection with certain medical products.

Rule 45 requires Plaintiffs to take reasonable steps to avoid imposing undue burden and expense on AdvaMed, a non-party to Plaintiffs' claims. On its face, the Subpoena falls well short of this requirement. The Subpoena seeks a broad array of AdvaMed's documents over a seven-year period and commands AdvaMed to produce an individual for deposition on a date unilaterally chosen and a mere three weeks after the subpoena was served. Complying with the Subpoena as written would impose a substantial burden on AdvaMed and would require AdvaMed to expend an enormous amount of time and financial resources. Plaintiffs have not established that they need AdvaMed to conduct these unduly burdensome searches, nor have

Plaintiffs demonstrated that the benefit of the documents that they seek outweighs the substantial burden on AdvaMed, a non-party. For these reasons, Plaintiffs have not met their burden under Rule 45.

Additionally, AdvaMed objects to the Subpoena to the extent that it seeks information protected from disclosure by the attorney-client privilege, attorney work product doctrine, or by any other applicable privilege or immunity from production. Specifically, AdvaMed objects on the ground that the Subpoena requests information protected by the First Amendment privilege as disclosure would infringe on AdvaMed's associational rights. Nothing contained in AdvaMed's objections and responses to the Subpoena is intended to be, or in any way should be deemed to be, a waiver of any such privilege or immunity. AdvaMed further objects to the subpoena's request for a deposition for all of the same reasons. Nonetheless, AdvaMed is willing to meet and confer with Plaintiffs regarding the scope of the Subpoena requests. AdvaMed has spoken previously with Plaintiffs' counsel in the *Ethicon* (MDL No. 2325) and *AMS* (MDL No. 2327) actions and has agreed to consolidate briefing to resolve the remaining disputes. AdvaMed is prepared to discuss such a schedule as soon as Plaintiffs are coordinated.

GENERAL OBJECTIONS

The following general objections apply to the Subpoena as a whole, and the Definitions and Requests for Production in Exhibit A to the Subpoena. The following general objections, unless otherwise stated, shall have the same force and effect as if set forth in full in the individual responses to each of the numbered document requests in Exhibit A to the Subpoena.

1. AdvaMed objects to the Subpoena to the extent that it imposes an undue burden upon AdvaMed by requesting information the value of which, if any, is substantially outweighed by the extensive burden and cost of searching for and compiling it.

2. AdvaMed objects to the Subpoena to the extent that it seeks to impose on AdvaMed any discovery obligation greater than or inconsistent with those imposed by the Federal Rules of Civil Procedure or by an order entered by the Court in this matter. AdvaMed assumes no duty to respond except as specifically required by the Federal Rules or an order of the Court.

3. Any inadvertent production of information protected by the attorney-client privilege, prepared in anticipation of litigation or trial, or otherwise protected or immune from discovery shall not constitute a waiver of any privilege or other basis for objecting to the production of such material or its subject matter. AdvaMed expressly reserves the right to object to the use or introduction of such information or otherwise to seek the return of such information.

4. AdvaMed objects to the Subpoena to the extent that it seeks information that is protected from disclosure by law, court order, confidentiality, or non-disclosure agreement, or the disclosure of which would violate the privacy rights of any of AdvaMed's officers, directors, employees, or members.

5. AdvaMed objects to the Subpoena to the extent that it seeks information that is a matter of public record, is equally available to the parties in the underlying action, or is already in a party's possession, custody, or control.

6. AdvaMed's objections and responses are made without waiving, in any way: (1) the right to object on any basis permitted by law to the use of any information provided in its responses for any purpose, in whole or in part, in the underlying action, in any subsequent proceeding in this action or in any other action; or (2) the right to object on any basis permitted by law to any other discovery request or proceeding involving or relating to the subject matter of AdvaMed's responses.

7. AdvaMed objects to the Subpoena to the extent that it seeks information that is not relevant to the claim or defense of any party in the underlying action and/or is not reasonably calculated to lead to the discovery of admissible evidence. By providing responses, AdvaMed does not concede that the information sought is relevant or reasonably calculated to lead to the discovery of admissible evidence.

8. AdvaMed objects to the Subpoena to the extent that it seeks information or documents that are not in AdvaMed's possession, custody, or control.

9. AdvaMed objects to the Subpoena because and to the extent that it is vague, ambiguous, and unclear, including the use of terms that are not defined and/or not otherwise susceptible to any single meaning.

10. The fact that AdvaMed has objected or responded to a document request is not intended to be and shall not be construed as a waiver of all or part of any objection not stated with respect to the request.

11. AdvaMed incorporates these general objections by reference to each and every request below.

OBJECTIONS TO DEFINITIONS

1. AdvaMed objects to the definition of the terms "documents" and "electronically-stored information" as vague and ambiguous, overbroad and unduly burdensome. AdvaMed further objects to this definition to the extent that it seeks information that is protected from disclosure by law, court order, confidentiality, or non-disclosure agreement, or the disclosure of which would violate the privacy rights of any of AdvaMed's officers, directors, employees, or members. AdvaMed further objects to the definition to the extent that it seeks information or documents that are not in AdvaMed's possession, custody, or control. AdvaMed further objects

to the definition to the extent that it seeks information protected from disclosure by the attorney-client privilege, attorney work product doctrine, First Amendment privilege, or by any other applicable privilege or immunity from production. AdvaMed also objects to this definition to the extent that it seeks information that is not relevant or reasonably calculated to lead to the discovery of admissible evidence. AdvaMed further objects to this definition to the extent it requires AdvaMed to produce electronically stored information in the absence of agreed-upon parameters for the production of electronically stored information. AdvaMed is willing to meet and confer with Plaintiffs to determine the appropriate production form for certain categories of documents, including electronically stored information.

SPECIFIC OBJECTIONS AND RESPONSES

Document Request No. 1

All documents concerning the risks, safety, or efficacy of transvaginal surgical mesh products from 2005 to present, including but not limited to the AdvaMed members and/or manufactures identified *supra* at 1-2.

Objections and Response to Document Request No. 1

AdvaMed incorporates its General Objections and its Objections to Definitions in response to Document Request No. 1. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request on the ground that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control.

Document Request No. 2

All documents concerning the preparation, presentation or attendance on behalf of AdvaMed or its transvaginal surgical mesh product manufacturer members during the Obstetrics and Gynecology Devices Panel of the United States Food and Drug Administration ("FDA")'s Medical Devices Advisory Committee held on September 8 and 9, 2011, including but not limited to:

a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled "Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse;"

b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;

c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;

d. The classification of the transvaginal surgical mesh products to Class III (Premarket Approval);

e. Discussion, analysis of, or reference to FDA's 510(k) decision or submission process, including science reports; and

f. Premarket and postmarket review protocols, policies, or procedures.

Objections and Response to Document Request No. 2

AdvaMed incorporates its General Objections and its Objections to Definitions in response to Document Request No. 2. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request on the ground that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control.

Document Request No. 3

All documents concerning the industry working group fanned by AdvaMed from 2005 to present, known as the "Transvaginal Mesh Industry Working Group," including but not limited to the following concerning transvaginal surgical mesh products:

a. Preparation of the Docket Submission to the September 8 and 9, 2011 Obstetrics and Gynecology Devices Panel entitled "Safety and Effectiveness of Transvaginal Surgical Mesh Used For Repair Of Pelvic Organ Prolapse;"

b. Scientific literature discussing the risks, safety and efficacy of transvaginal surgical mesh products;

c. Premarket clinical and preclinical studies, and postmarket studies evaluating the safety and effectiveness of transvaginal surgical mesh for the treatment of pelvic organ prolapse or stress urinary incontinence;

d. The declassification of the transvaginal surgical mesh products to Class III (Premarket Approval);

e. Discussion, analysis of, or reference to FDA's 510(k) decision or submission process, including science reports;

f. Premarket and postmarket review protocols, policies, or procedures;

g. Meeting minutes, notes or memoranda from organizational group meetings; and

h. Any communications and submissions made in anticipation to or in response to otherwise relating to the FDA's "Section 522 Order" issued in January 2012.

Objections and Response to Document Request No. 3

AdvaMed incorporates its General Objections and its Objections to Definitions and in response to Document Request No. 3. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed further objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control. AdvaMed also objects to this request to the extent that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege.

Document Request No. 4

All documents by AdvaMed or its member companies' relating to communications and submissions with or to legislators, regulators, domestic and foreign governmental bodies, health care providers, medical societies and patient organizations, concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process, of transvaginal surgical mesh products from 2005 to present.

Objections and Response to Document Request No. 4

AdvaMed incorporates its General Objections and its Objections to Definitions and in response to Document Request No. 4. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed further objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control. AdvaMed also objects to this request to the extent that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege.

Document Request No. 5

All documents or communications concerning the risks, safety and efficacy of transvaginal surgical mesh products presented by AdvaMed at any medical technology conference from 2005 to present.

Objections and Response to Document Request No. 5

AdvaMed incorporates its General Objections and its Objections to Definitions and in response to Document Request No. 5. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed further objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control. AdvaMed also objects to this request to the extent that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege.

Document Request No. 6

All documents communicated by AdvaMed or its transvaginal surgical mesh product manufacturer members with the medical relations organization "newsPRo," concerning the risks, safety, efficacy, or the FDA 510(k) decision or submission process of the transvaginal surgical mesh products from 2005 to present.

Objections and Response to Document Request No. 6

AdvaMed incorporates its General Objections and its Objections to Definitions and in response to Document Request No. 6. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed further objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control. AdvaMed also objects to this request to the extent that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege.

Document Request No. 7

All documents relating to the FDA's "Section 522 Order" issued in January 2012.

Objections and Response to Document Request No. 7

AdvaMed incorporates its General Objections and its Objections to Definitions and in response to Document Request No. 7. AdvaMed objects to this request on the ground that it is vague and ambiguous and contains undefined terms. In addition, AdvaMed objects to this request on the grounds that it is overbroad and unduly burdensome, particularly to the extent it seeks "all documents" responsive to this topic. Plaintiffs have not articulated why they need "all documents" responsive to this request, as opposed to a narrower set of documents, and therefore have not met their obligation under Rule 45 of the Federal Rules to avoid imposing undue burden and expense on AdvaMed. AdvaMed further objects to this request to the extent it seeks information that is not relevant to the claim or defense of any party in the above-captioned proceeding or is not reasonably calculated to lead to the discovery of admissible evidence. AdvaMed also objects to this request to the extent it requests documents that are already in a party's possession, custody, or control and/or documents that are not in AdvaMed's possession, custody, or control. AdvaMed also objects to this request to the extent that it seeks competitively sensitive and confidential business information and/or information protected by the attorney-client privilege, work product doctrine, First Amendment privilege, or any other privilege.

Dated: January 23, 2013

Respectfully submitted,

//s// Allen M. Gardner

Allen M. Gardner
Andrew J. Robinson
LATHAM & WATKINS LLP
555 Eleventh Street, N.W., Suite 1000
Washington, D.C. 20004-1304
Telephone: (202) 637-2200
Facsimile: (202) 637-2201
Email: Allen.Gardner@lw.com

Attorneys for AdvaMed

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on January 23, 2013, I caused a true and correct copy of the foregoing to be served by email and Federal Express on the following counsel identified in the Subpoena:

Aimee Wagstaff
ANDRUS HOOD & WAGSTAFF, PC
1999 Broadway, Suite 4150
Denver, Colorado 80202
Aimee.wagstaff@ahw-law.com

Clayton A. Clark
CLARK LOVE & HUTSON, GP
440 Louisiana Street, Suite 1600
Houston, Texas 77002
CClark@triallawfirm.com

//s// Allen M. Gardner
Allen M. Gardner